

BB-1145
TXR-6285

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MEMORANDUM

DATE: August 9, 1985

SUBJECT: EPA Registration Number 476-2216
LC-6641 Selective Herbicide

FROM: Deloris F. Graham *NFA 8/16/85*
FHB/TSS *E 8/16/85*

TO: Robert Taylor
Product Manager (25)

Applicant: Stauffer Chemical Company
1200 S. 47th Street
Richmond, CA 94804

Active Ingredient:

| | |
|--|--------|
| S-Ethyl diisobutythiocarbamate | 58.80% |
| Atrazine: 2-Chloro-4-(ethylamino) | |
| -6-(isopropylamino)-s-triazine | 14.30% |
| Related triazines | 0.40% |
| Inert Ingredients | 26.50% |

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies on this product. Submitted Acute Inhalation and Dermal Sensitization Studies on EPA Registration Number 476-2213. Studies conducted by Stauffer Chemical Company, Richmond Toxicology Laboratory, and WIL Research Laboratories, Inc. Data under Accession Number 254800. Method of support not indicated.

Recommendation:

1. FHB/TSS finds these data acceptable to support conditional registration of this product.
2. The appropriate signal word is DANGER.

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Label:

1. The statement "This product may cause allergic skin reaction" must be included in precautionary statements.

Review:

1. Acute Oral Toxicity Study: Richmond Toxicology Laboratory; Study No. T-12119, September 13, 1984.

Procedure: Ten male rats received 5000 mg/kg of the test material orally. Observations made for 14 days posttreatment. Necropsy performed on all animals. A control group of 10 rats was treated in similar manner as test group except no test substance used.

Results: One out of 10 male rats died. Toxic signs reported included mild to moderate depression, ptosis, lacrimation, salivation, reddish facial stains, piloerection, stained fur, reddish stained muzzles, reddish and/or darkened anogenital stains. Necropsy report revealed salivation, yellow-red anogenital stains, a red stained muzzle, reddened lungs, darkened liver, pale kidneys and spleen, greenish fluid in intestines, creamy fluid in the stomach, dark patches in stomach mucosa in animal that died during study. Necropsy of surviving animals indicated no abnormalities. LD₅₀ reported to be greater than 5000 mg/kg. No mortalities, clinical signs nor abnormalities reported in controls.

Study Classification: Core Guideline Data when used in conjunction with following Acute Oral Study.

Toxicity Category: IV - CAUTION

- (2) Acute Oral Toxicity Study: Richmond Toxicology Laboratory; Study No. T-12119; September 13, 1984.

Procedure: One group consisting of 20 female rats received a single oral dose of 5000 mg/kg. Three groups consisting of 10 female rats each received one of the following doses orally: 2712, 3162, or 3981 mg/kg. Observations were made for 14 days after treatment. Necropsy performed on all animals. A group of 10 female rats were treated in similar manner as previously stated except no test material used; this group served as control.

Results: At 2712 mg/kg, 1/10F died, at 3162 mg/kg, 4/10F died; at 3981 mg/kg, 6/10F died; at 5000 mg/kg, 13/20F died.

Toxic signs reported included mild to moderate depression, ataxia, ptosis, salivation, reddish facial stains, piloerection; wet, yellowish anogenital stains, prostration, rapid respiration, stained fur, lacrimation, chromodacryorrhea, hypersensitivity, hunched posture, stained and/or matted fur, and alopecia.

Necropsy report revealed yellowish anogenital stains, red stained muzzle, salivation, reddened lungs, test material-like substance in the stomach, pale kidneys, yellowish gelatinous fluid in the intestines; three rats cannibalized and not necropsied, pale livers dark-tipped spleen, pale uterine horns, darkened adrenals.

LD₅₀ for females reported to be 3833 mg/kg with confidence limits between 3297 and 4455 mg/kg.

Study Classification: Core Guideline Data when used in conjunction with preceding acute oral study.

Toxicity Category: III-CAUTION

(3) Acute Dermal Toxicity Study:

Richmond Toxicology Laboratory; Study No. T-12119;
September 13, 1984.

Procedure: Five male and 5 female rabbits received 2000 mg/kg of the test material under occlusive wrap for 24-hour exposure period. One-half animals had abraded skin. Observations made for 14 days after treatment. Necropsy performed on all animals. A group of two male and two female animals were treated in similar manner as previous group except no test substance used; these animals served as controls.

Results: No mortalities or abnormalities at necropsy reported. Toxic signs reported included mild to moderate depression only, mild to moderate erythema and moderate to severe edema. Control animals appeared normal throughout the study. LD₅₀ reported to be greater than 2000 mg/kg.

Study Classification: Core Guideline Data

Toxicity Category: III-CAUTION

(4) Skin Irritation Study: Richmond Toxicology Laboratory;
Study No. T-12119; September 13, 1984.

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Procedure: Six rabbits received 0.5 ml of the test material at abraded and intact skin sites under occlusive wrap for 4-hour exposure period. Observations made at 4, 24 and 72 hours after treatment.

Results: At 24 hours, 5/6 mild to moderate erythema (scores of 1 and 2) and 1/6 mild edema (scores of 1). At 72 hours, 5/6 mild to moderate erythema (scores of 1 and 2) and 2/6 mild edema (scores of 1). It was reported that on day 7 superficial sloughing at dose sites of four rabbits. Primary Irritation Score reported to be 1.03.

Study Classification: Core Guideline Data

Toxicity Category: III-CAUTION

(5) Eye Irritation Study: Richmond Toxicology Laboratory; Study No. T-12119; September 13, 1984.

Procedure: Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed with water 20-30 seconds after treatment. Observations made at 1, 24, 48 and 72 hours after treatment and at 4 to 7 days. If irritation persisted at 7 days, observations were made every 3 or 4 days until irritation subsided or was found irreversible.

Results: At day 1, 6/6 unwashed group had corneal opacity (1/6=15, 5/6=20); iris irritation (2/6=5, 4/6=10); conjunctive redness (1/6=2, 5/6=3), chemosis (6/6=1) and discharge (2/6=2, 4/6=3). At day 7, 5/6 corneal opacity (2/6=5, 2/6=10, 1/6=20); 2/6 iris irritation (2/6=5); 3/6 redness (1/6=1, 2/6=2) and 2/6 discharge (2/6=2). At day 14, 2/6 corneal opacity (1/6=5, 1/6=80); 1/6 could not be scored for iris irritation due to corneal opacity and 5/6=0; 1/6 redness (1/6=2) and discharge (1/6=2). At day 21, 2/6 corneal opacity (1/6=5, 1/6=80); 1/6 redness (1/6=1). At day 24, 2/6 corneal opacity (1/6=5, 1/6=60); 1/6 redness (1/6=1).

At day 1, 1/3 animals of washed group had corneal opacity (1/3=5) and iris irritation (1/3=5); 3/3 conjunctive redness (3/3=2) and chemosis (3/3=1); 2/6 discharge (2/6=1). Irritation and corneal opacity had cleared by day 7.

Mild to severe corneal epithelial erosion, neovascularization and pannus were also noted.

Study Classification: Core Guideline Data

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Toxicity Category: I-DANGER

(6) Acute Inhalation Toxicity Study: Stauffer Chemical Company;
Study No. T-11778; September 14, 1983.

Procedure: Ten male and 10 female rats were exposed for 4 hours to a mean concentration of 6.43 mg/l. Particle size ranged from 2.05 to 2.81 μ . Mean temperature was reported to be 22.5 ± 0.3 . Relative humidity 100 ± 1 percent. Observations made during exposure, then for 14 days after exposure. Necropsy performed on all animals. A group of 10 male and 60 female rats were treated in similar manner as previous group except no test material used; these animals served as controls.

Results: No mortalities noted. Clinical signs reported included wet coats, red stains, pigmented nasal secretion and salivation. No abnormalities reported at necropsy related to test material. However red foci in lungs and kidney-dilated pelvis in test and control groups.

Study Classification: Core Guideline Data

Toxicity Category: IV-CAUTION

(7) Dermal Sensitization Study: WIL Research Laboratories, Inc.;
Study No.: WIL-27016; October 5, 1983.

Procedure: One group consisting of 10 male and 10 female guinea pigs received 0.4 ml of a 25 percent concentration of the test material once a week for 3 weeks via patch application during induction phase. Two weeks following third application animals received a 0.4 ml dose of a 10 percent concentration as challenge dose. Observations made at 24 and 48 hours after each application. Another group, consisting of five male and five female guinea pigs, served as naive control.

Results: Mild to moderate erythema noted during induction phase of test group and at challenge dose with irritation more pronounced at 48 hours after application than at 24 hours after. Slight irritation noted at challenge dose of naive control group. Therefore it was concluded that sensitizing reaction had occurred.

Study Classification: Core Guideline Data

Toxicity Category: Skin sensitizer

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Butylate toxicology review

Page _____ is not included in this copy.

Pages 6 through 9 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients
 - ☐ Identity of product impurities
 - ☐ Description of the product manufacturing process
 - ☐ Description of product quality control procedures
 - ☐ Identity of the source of product ingredients
 - ☐ Sales or other commercial/financial information
 - ☒ A draft product label
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